**Sedation Consortium on Endpoints and Procedures for Treatment, Education, and Research**

**(SCEPTER-III)**

**Clinical Trials to Evaluate Patient-Centered Outcomes of Sedation in Mechanically Ventilated Patients in the Adult ICU**

**MEETING AGENDA**

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| **Wednesday, March 27, 2019** | | |
| **7:00 – 9:00 PM** | **Reception and Dinner** | **Mayfair Court** |
| **Thursday, March 28, 2019** | | |
| **7:30 – 8:00 AM** | **Continental Breakfast** |  |
| 8:00 – 8:30 | Welcome and Introductions | Bob Dworkin |
| 8:30 – 8:45 | Procedural Sedation – SCEPTER 1 & 2. Goals for SCEPTER 3 | Denham Ward |
| 8:45 – 10:00 | Panel Discussion: Current Clinical Guidelines - SCCM PADIS guidelines: Pain, Agitation/Sedation, Delirium, Immobility and Sleep Impairment | Douglas Coursin (moderator), John Devlin  Yoanna Skrobik |
| 10:00 – 10:30 | Break |  |
| 10:30 – 11:00 | Patient and family perspective | David Brown |
| 11:00 – 11:30 | Establishing core outcome measures and instruments: a case study in evaluating post-discharge status of ICU survivors | Dale Needham |
| 11:30 – 12:00 | Q&A and Panel discussion: How to incorporate the patient’s and families’ perspective | Pam Flood (moderator), David Brown, Dale Needham, Ingrid Egerod |
| **12:00 – 1:00 PM** | **Lunch** | **Mayfair Court** |
| 1:00 – 1:30 | SEDCOM, MENDS, MIDEX & PRODEX – Lessons learned for study design, outcomes and measures | Richard Riker |
| 1:30 - 2:00 | Evaluating efficacy in ICU sedation clinical trials: a regulatory perspective | Martha Van Clief |
| 2:00 - 2:30 | Q&A and panel discussion: current controversies, and unmet needs | Gil Fraser, Douglas Coursin (moderators), Yoanna Skrobik, Mervyn Maze, Richard Riker, Martha Van Clief |
| 2:30 -3:00 | Break |  |
| 3:00 - 3:30 | Design issues for clinical trials of ICU sedation | Daniel Sessler |
| 3:30 - 4:00 | Clinical Trials for new ICU Sedation Protocols | Leanne Aitken |
| 4:00 - 4:30 | Statistical issues in clinical trial design for ICU sedation | Elizabeth Colantuoni |
| 4:30 – 5:00 | Q&A and Panel discussion: Clinical trial design | Steve Shafer(moderator), Daniel Sessler, Leanne Aitken, Franklin Dexter, Elizabeth Colantuoni, Yahya Shehabi |
| **7:00 – 9:00** | **Dinner** | **Mayfair Court** |

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| **Friday, March 29, 2019** | | |
| **7:30 – 8:00 AM** | **Continental Breakfast** | **Washington Ballroom** |
| 8:00 – 8:30 | Defining and measuring light vs moderate sedation / analgesia | Pratik Pandharipande |
| 8:30 – 9:00 | Case Study: Approval of Dexmed for ICU sedation | Mervyn Maze |
| 9:00 – 10:00 | Who should be studied and how?   * Controls and patient inclusion / exclusion criteria? * Overall trial design. | Avery Tung (moderator) |
| 10:00 – 10:30 | **Break** |  |
| 10:30 – 12:00 | Evaluating acute use of ICU sedation / analgesia.   * How best to measure level of sedation? * Patient and family perspective. * Sleep state? * Efficacy of the sedation / analgesia? * Safety measures during sedation? | Yoanna Skrobik (moderator) |
| 12:00 – 1:00 | **Lunch** | **Mayfair Court** |
| 1:00 – 2:30 | Acute, Subacute and chronic outcomes after ICU sedation.   * Sedation outcome domains, measures, and items? * Improving medical outcomes, short term and post discharge? * Outcomes that are more likely to have a strong correlation with sedation? | Tim Girard (moderator) |
| 2:30 – 3:00 | Group Discussion: SCEPTER 3 next steps | Denham Ward |